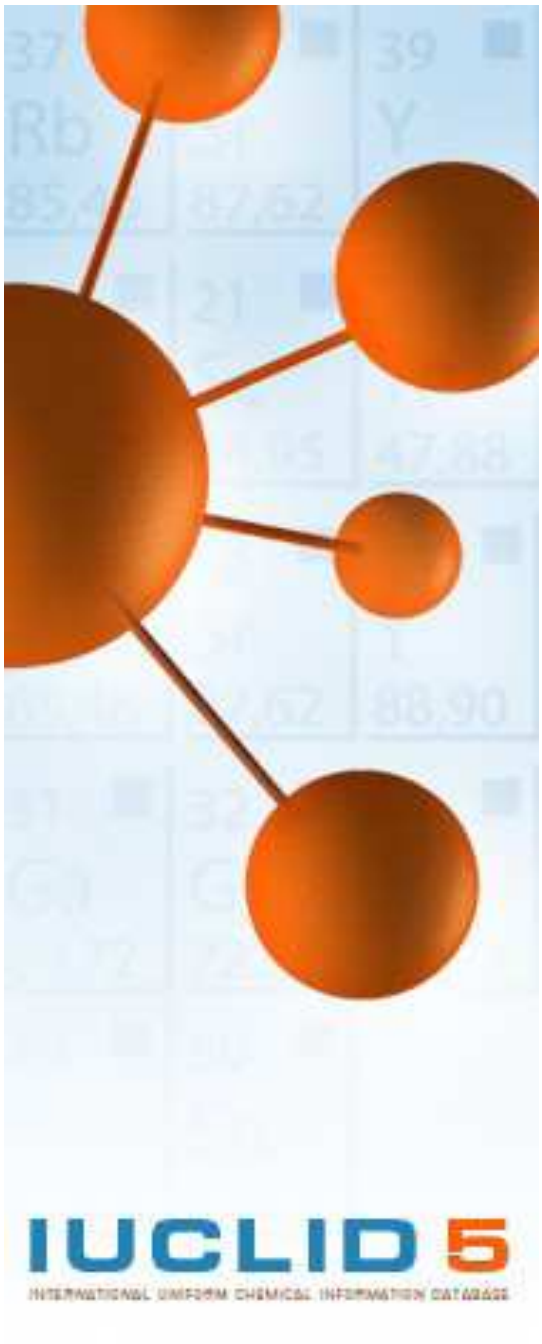

IUCLID 5
Guidance and Support

IUCLID 5
Technical Completeness Check Plug-in
User Manual

July 2012 v1.5

IUCLID 5 is developed by the European Chemicals Agency in association with the Organisation for Economic Co-operation and Development

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1 Principle of the Technical Completeness Check (TCC) plug-in

1.1 Technical completeness check

According to the REACH Regulation, registration dossiers and PPORD notifications are subject to a completeness check (Article 20(2)). This completeness check can be divided in two parts: the Financial Completeness Check (FCC) and the Technical Completeness Check (TCC).

The aim of the Technical Completeness Check (TCC) plug-in is to enable registrants and PPORD notifiers to check within their IUCLID 5 installation (or database) the technical completeness of their dossiers (or substance datasets) prior a submission to ECHA via REACH-IT. The plug-in also checks that a dossier (or substance dataset) will be able to pass some of the business rules.

⚠ **Note:** Although the plug-in simulates the technical completeness check carried out by ECHA to the largest extent possible, it will not be able to capture exhaustively all possible scenarios in which a dossier may be found incomplete (e.g. resulting from different tonnage bands of lead and member dossiers in a joint submission). The responsibility remains with the company ensure that their submission fulfils all the relevant legal requirements.

Please refer to Data Submission Manual 5 “How to complete a technical dossier for registrations and PPORD notifications” for detailed information on how to fill in the minimum requirements in IUCLID 5. The manual is available at http://echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/data-submission-industry-user-manuals.

1.2 Business rules check

The TCC plug-in incorporates several of the business rules (BR) checked at ECHA. The following REACH dossier types are supported for business rules check: Registration, Downstream user report, PPORD-, Substance in article- and Inquiry notification. In addition, the business rules check is available for the dossier types CLP notification and CLP alternative name request. From version 5.4.0 onwards, the TCC plug-in also supports the business rules check for dossiers submitted by Authorities, namely Substance Evaluation dossiers, REACH Annex XV proposals (restriction and SVHC) and CLP Annex VI (CLH) proposals.

⚠ **Note:** As some of the business rules depend on information that is stored within the REACH-IT database, the plug-in cannot simulate all the business rules checked at ECHA.

For further information on the business rule check, please refer to Data Submission Manual 4: “How to Pass Business Rule Verification ("Enforce Rules")”, available at:
http://echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/data-submission-industry-user-manuals.

1.3 Substance identity check

The TCC plug-in also features a module for improved check of inquiry dossiers. The so-called substance identity (SID) check has been designed to assist companies in the preparation of inquiry dossiers. It enables potential registrants to identify which fields in IUCLID should be filled in or deserve particular attention. The SID check (together with the inquiry business rules), is automatically executed when the TCC plug-in is run on a dossier built on the inquiry template. Similarly, the SID check (and the inquiry BR check) can also be carried out on a substance dataset by selecting the option ‘Substance identity check’ in the TCC wizard.

⚠ **Note:** The substance identity check carried out by the plug-in does not provide an assessment of the adequacy of the information reported. The use of this tool is without prejudice to the expert assessment carried out by ECHA to establish the adequacy of the information required under Annex VI Section 2 of the REACH Regulation. This responsibility lies with the submitter of the inquiry.

Please refer to Data Submission Manual 2: "How to prepare and submit an inquiry dossier" for information on how to fill in the minimum requirements for an inquiry dossier in IUCLID 5. The manual is available at http://echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/data-submission-industry-user-manuals.

For further information on the description of substances in IUCLID 5, please refer to Data Submission Manual 18: "How to report the substance identity in IUCLID 5 for registration under REACH", available at: http://echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/data-submission-industry-user-manuals and "Guidance for identification and naming of substances under REACH and CLP", available at: http://echa.europa.eu/guidance-documents/guidance-on-reach.

2 Adding the plug-in to your local IUCLID 5 installation

The plug-in is based on a server side and a client side ZIP file called:

- eu.echa.iuclid.**client**.plugin.tccvalidate.ui.zip
- eu.echa.iuclid.**server**.plugin.tccvalidate.zip

The installation of the plug-in depends on your IUCLID 5 installation:

- workstation / stand-alone version or
- distributed version

2.1 Workstation / stand-alone installation

If you have installed the IUCLID 5 stand-alone software in the folder

C:\ IUCLID5

You will find the sub-folders:

C:\IUCLID5\plugins\client	(folder for the client side plug-ins)
C:\IUCLID5\plugins\server	(folder for the server side plug-ins)

To install the plug-in you need to copy the above-mentioned client and server side zip-files into the appropriate folders (see examples below in the table).

⚠ **Note:** For the plug-in to work properly, both of the zip-files must be copied into their respective folders – it is not enough to copy only the client side zip-file.

Important:

Do not extract the ZIP files!
Depending on your computer setting the file name may be displayed without extension (.zip).

Copy the file	eu.echa.iuclid.**client**.plugin.tccvalidate.ui.zip
into the folder	<IUCLID5-folder>**\plugins\client**
Sample	C:\IUCLID5\plugins\client\eu.echa.iuclid.client.plugin.tccvalidate.ui.zip
Hint	In the folder you will already find files like: - ClientExtensionPointRootPlugin.zip - eu.echa.iuclid.plugin.helpsystemEN.zip - eu.echa.iuclid.plugin.xform.zip

Copy the file	eu.echa.iuclid.**server**.plugin.tccvalidate.zip
into the folder	<IUCLID5-folder>**\plugins\server**
Sample	C:\IUCLID5\plugins\server\eu.echa.iuclid.server.plugin.tccvalidate.zip
Hint	In the folder you will already find files like: - ServerExtensionPointRootPlugin.zip - eu.echa.iuclid.plugin.resources.zip

The plug-in will be available after **re-starting your IUCLID 5 application**.

Tip:

If the plug-in is no longer required, the files can be removed from the folders. The plug-in will disappear from the IUCLID 5 application.

2.2 Distributed installation

You will find the sub-folders on your IUCLID 5 application server:

...\i5clientPlug-ins\remotePlugins (folder for the client side plug-ins)

...\WEB-INF\classes\plugins (folder for the server side plug-ins)

To install the plug-in you need to copy the above-mentioned client and server side zip-files into the appropriate folders (see examples below in the table).

Important:

Do not extract the ZIP files!
Depending on your computer setting the file name may be displayed without extension (.zip).

Copy the file	eu.echa.iuclid.**client**.plugin.tccvalidate.ui.zip
into the folder	<IUCLID5 WebApp-folder>**\i5clientPlugins\remotePlugins**
Sample	C:\Program Files\apache-tomcat\webapps\i5server\ i5clientPlugins\remotePlugins\eu.echa.iuclid.client.plugin.tccvalidate.ui.zip
Hint	In the folder you will already find files like: - ClientExtensionPointRootPlugin.zip - eu.echa.iuclid.plugin.helpsystemEN.zip - eu.echa.iuclid.plugin.xform.zip

Copy the file	eu.echa.iuclid.**server**.plugin.tccvalidate.zip
into the folder	<IUCLID5 WebApp-folder>**\WEB-INF\classes\plugins**
Sample	C:\Program Files\apache-tomcat\webapps\i5server\ WEB-INF\classes\plugins\eu.echa.iuclid.server.plugin.tccvalidate.zip
Hint	In the folder you will already find files like: - ServerExtensionPointRootPlugin.zip - eu.echa.iuclid.plugin.resources.zip

The plug-in will be available after **re-starting your IUCLID 5 application as well as your server (e.g. TOMCAT).**

Tip:

If the plug-in is no longer required, the files can be removed from the folders. The plug-in will disappear from the IUCLID 5 application.

3 Launching the TCC plug-in

After the installation of the plug-in the new functionality is available in IUCLID 5:

➢ In the task pane, in the part 'Plug-ins'

Figure 1: TCC plug-in run button

➢ In the main menu of IUCLID 5

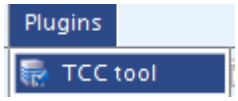


Figure 2: TCC plug-in via menu item

➢ In the toolbar

Figure 3: TCC toggle button

A click on this toggle button in the toolbar hides or displays the TCC window, e.g. it allows the user to modify a substance dataset without losing the settings defined for the TCC check.

➢ In the 'Query' window of your list of dossiers or substances

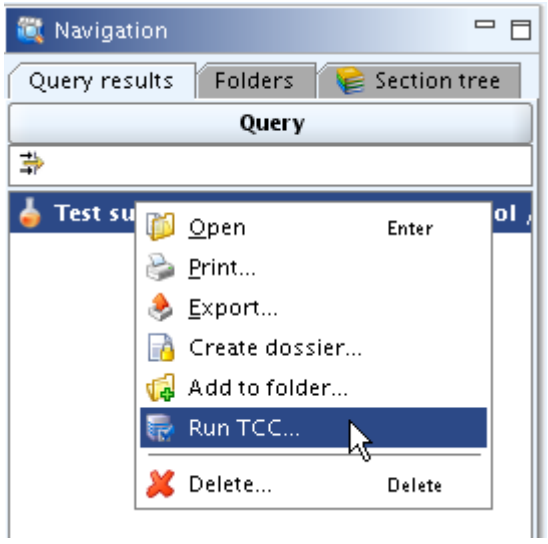


Figure 4: Run TCC option

In the 'Substance' or 'Dossier' menu, right-click the name of the substance dataset or dossier in the 'Query' window and select 'Run TCC'. This is a convenient way to launch the completeness check of the substance dataset or the dossier right after modifying/creating it without having to search for it. Furthermore, since the completeness check can be launched from the same location where dossier creation (in the case of a substance dataset) or dossier export (in the case of a finished dossier) takes place, the possibility of checking the incorrect substance/dossier is reduced.

4 Using the TCC plug-in

This section explains how to use the TCC plug-in to check the completeness of a dossier or a substance dataset. Depending on the dossier type, the dossier content is assessed through business rules checks, technical completeness checks or substance identity checks, or their combinations.

Click on in the Task pane to go Home if you are not already there. Start the TCC wizard as described above.

4.1 STEP 1: select the dossier/substance

The first step in the wizard is to choose the document to be checked by clicking on the icon.

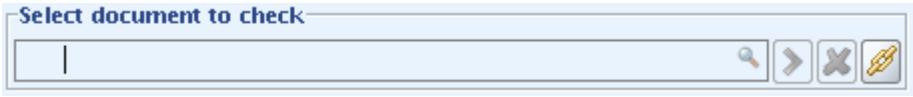


Figure 5: Entry field 'Select document to check'

This will open a query window where it will be possible to select either a dossier or a substance (the TCC plug-in can be used to check the completeness of dossiers or of substance datasets).

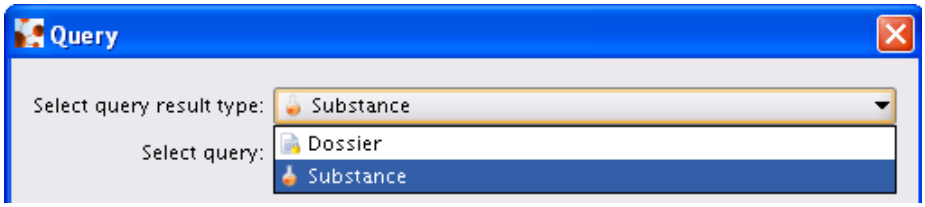


Figure 6: Query selection

4.1.1 Checking dossiers (all supported dossier templates)

When the TCC plug-in is launched on a dossier, it will by default perform a check according to the dossier template used. For dossiers built on the templates REACH Registration and REACH PPORD, this means that both a technical completeness check and a business rules check are performed. Similarly, for dossiers built on the template REACH Inquiry, both a substance identity check and a business rules check are carried out. For the remaining templates supported by the plug-in (see section 1), only a business rules check is performed. When running the technical completeness check on a REACH Registration dossier, the plug-in furthermore uses the tonnage band information from the dossier template and header, and applies the appropriate technical completeness rule set.

⚠⚠ **Important note:** For all types of dossiers, it is strongly recommended to run the TCC plug-in on the final dossier prior to submitting it in REACH-IT.

4.1.2 Checking substance datasets (for registration, PPORD, inquiry)

Unlike dossiers, substance datasets do not correspond to a specific type of submission and therefore the user needs to select which rules need to be applied for the TCC. If the substance has to be checked in order to create a PPORD notification dossier, select the radio button 'PPORD notification'. Similarly, if the substance dataset will be used for the preparation of an inquiry dossier, select the radio button 'Substance identity check (for inquiry notification)'. Otherwise, leave the box 'Registration dossier templates' selected (selection done by default) and when you press the 'Next' button you will be directed to a new screen where you can select the type of registration dossier you would like to perform the TCC on (see Step 2 below).

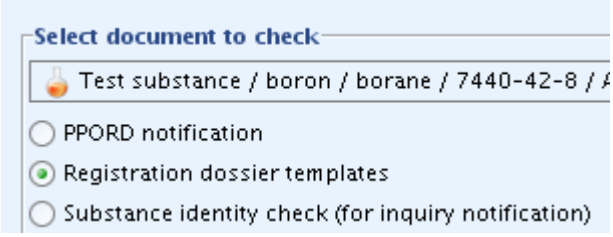
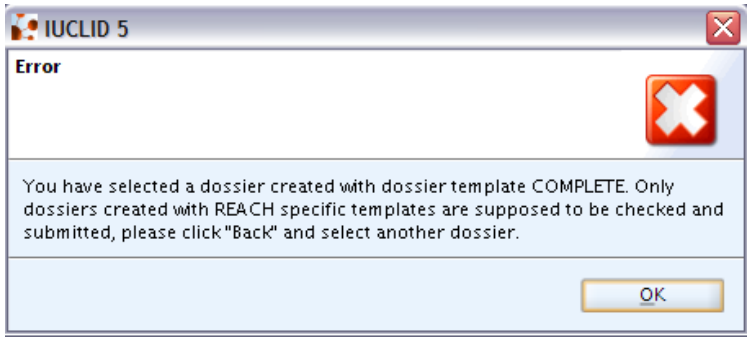

Select document to check
Test substance / boron / borane / 7440-42-8 / A
PPORD notification
Registration dossier templates
Substance identity check (for inquiry notification)

Figure 7: Radio button for dossier type

⚠⚠ **Important note:** A IUCLID 5 dossier consists of two parts: a substance dataset, and the so called dossier header. The dossier header has to be generated during the dossier creation process, and it contains certain relevant information about the dossier, such as the tonnage band covered by the registration. The Technical Completeness Check also verifies the presence of certain information in the dossier header. However, this information can only be checked for dossiers, since a substance dataset does not contain a dossier header. Therefore, even if your substance dataset is considered complete by the plug-in, it is very important that you check also the dossier you have generated from the substance dataset to verify that the dossier header is also complete.

⚠ **Note:** Please keep in mind that this plug-in has been designed to validate the technical completeness of REACH registration dossiers and PPORDs. In addition, the REACH templates for Inquiry, Downstream user report and Notification of substance in article, and the CLP templates for CLP notification and CLP alternative name request, are supported for a partial business rules check. The plug-in also supports the business rules check for the following dossier types submitted by Authorities: Substance Evaluation, REACH Annex XV - Restriction, REACH Annex XV - SVHC and CLP Regulation - CLH dossier. If the validation is started on a dossier created with another dossier template the process aborts with an error similar to the one shown below:


IUCLID 5
Error
You have selected a dossier created with dossier template COMPLETE. Only dossiers created with REACH specific templates are supposed to be checked and submitted, please click "Back" and select another dossier.
OK

The user must also define if the dossier is for a phase-in or for a non phase-in substance. If the user wants to claim a fee waiver, this must also be indicated. By default, the settings of the plug-in are for a phase-in substance with no fee waiving claimed. In addition, to check that the relevant 'Regulatory programme identifiers' are entered in IUCLID 5 section 1.3, the user should indicate the update status of the dossier to be submitted

Note: the fee waiver can only be claimed in the case stated in REACH Article 74(2).

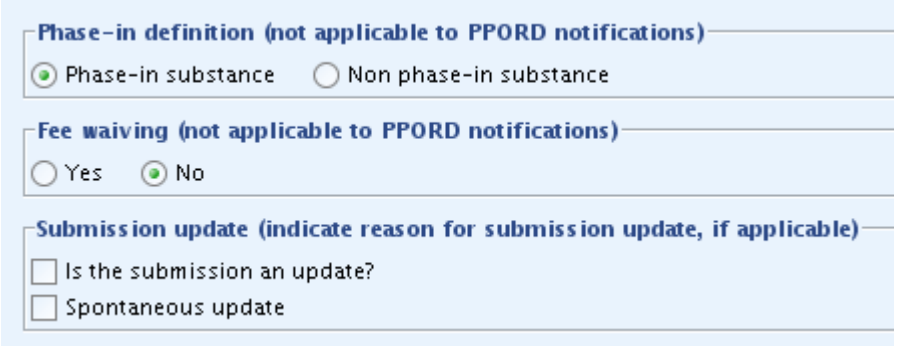

Phase-in definition (not applicable to PPORD notifications)
Phase-in substance
Non phase-in substance
Fee waiving (not applicable to PPORD notifications)
Yes
No
Submission update (indicate reason for submission update, if applicable)
Is the submission an update?
Spontaneous update

Figure 8: Selection of phase-in definition, fee waiving and update status

Once all the necessary definitions are done the user can proceed to the next step by clicking on the 'Next' button. If you select 'Registration dossier templates', you will be directed to step 2 (where further parameters need to be specified). If you select 'PPORD notification' or 'Substance identity check' you will be directed directly to step 3 where the results of the check are displayed.

4.2 STEP 2: select the template (only for registration substance datasets)

In this step the user has to define which template should be used for the TCC, i.e. the tonnage band of the registration dossier, if it is part of a joint submission and if it covers intermediate uses or not. After these parameters are defined, the 'Next' button becomes active.

4.2.1 Individual registration

If you are preparing a dossier that is not part of a joint submission, select the radio button 'No' under the heading 'Joint submission' and then use the picklists 'Registration dossier' and 'Intermediates' to indicate the relevant tonnage band. In the exceptional case of preparing a combined dossier, i.e. a registration dossier that covers both the use of a substance as an intermediate as well as non-intermediate use, select the appropriate tonnage bands from both picklists.

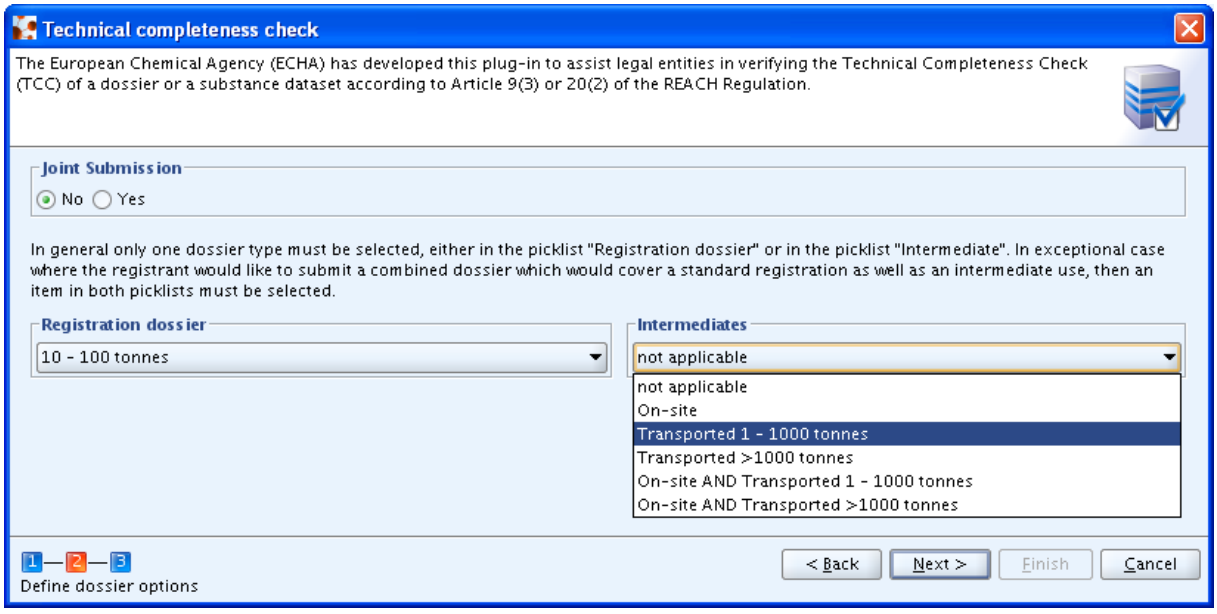

Technical completeness check
The European Chemical Agency (ECHA) has developed this plug-in to assist legal entities in verifying the Technical Completeness Check (TCC) of a dossier or a substance dataset according to Article 9(3) or 20(2) of the REACH Regulation.
Joint Submission
No
Yes
In general only one dossier type must be selected, either in the picklist "Registration dossier" or in the picklist "Intermediate". In exceptional case where the registrant would like to submit a combined dossier which would cover a standard registration as well as an intermediate use, then an item in both picklists must be selected.
Registration dossier
10 - 100 tonnes
Intermediates
not applicable
not applicable
On-site
Transported 1 - 1000 tonnes
Transported >1000 tonnes
On-site AND Transported 1 - 1000 tonnes
On-site AND Transported >1000 tonnes
1 2 3
Define dossier options
< Back
Next >
Finish
Cancel

Figure 9: Selection of tonnage band for an individual registration

4.2.2 Lead of a joint submission

If you are preparing the lead dossier for a joint submission, select the radio button 'Yes' under the heading 'Joint submission'. The heading 'Role in the joint submission' will appear. Set the radio button to 'Lead registrant of a joint submission' and then select the tonnage band(s) for your dossier using the picklists 'Registration dossier' and 'Intermediates'.

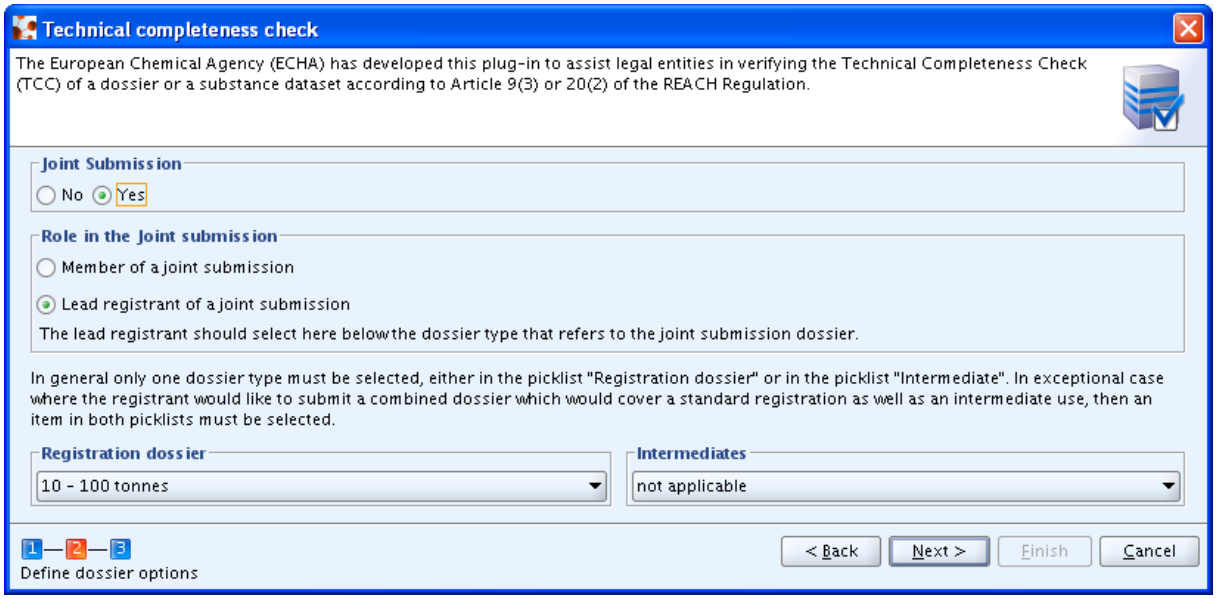

Technical completeness check
The European Chemical Agency (ECHA) has developed this plug-in to assist legal entities in verifying the Technical Completeness Check (TCC) of a dossier or a substance dataset according to Article 9(3) or 20(2) of the REACH Regulation.
Joint Submission
No
Yes
Role in the Joint submission
Member of a joint submission
Lead registrant of a joint submission
The lead registrant should select here below the dossier type that refers to the joint submission dossier.
In general only one dossier type must be selected, either in the picklist "Registration dossier" or in the picklist "Intermediate". In exceptional case where the registrant would like to submit a combined dossier which would cover a standard registration as well as an intermediate use, then an item in both picklists must be selected.
Registration dossier
10 - 100 tonnes
Intermediates
not applicable
1—2—3
Define dossier options
< Back
Next >
Finish
Cancel

Figure 10: Selection of tonnage band for a joint submission lead registration

4.2.3 Member of a joint submission

Select the radio button 'Yes' under the heading 'Joint submission'. Set the radio button for block 'Role in the joint submission' to 'Member of a joint submission' and then select the tonnage band(s) for your dossier using the picklists 'Registration dossier' and 'Intermediates'. For a correct outcome of the TCC tool, you should also indicate if the 'Chemical Safety Report' and 'Guidance on safe use' are provided by the lead registrant on your behalf or if they are included in your dossier.

Please note also that you should make a selection in the picklist 'Tonnage band of the joint submission'.

⚠ **Note:** For the endpoint sections (section 4 to 8 of IUCLID 5) a dossier for a member of a joint submission should normally contain only endpoint study records for those endpoints for which the member opts out from the joint submission. In the same manner, the member dossier should not contain any Classification and Labelling information (IUCLID 5 sections 2.1 and 2.2) unless the member indicates that they are opting out for the C&L.

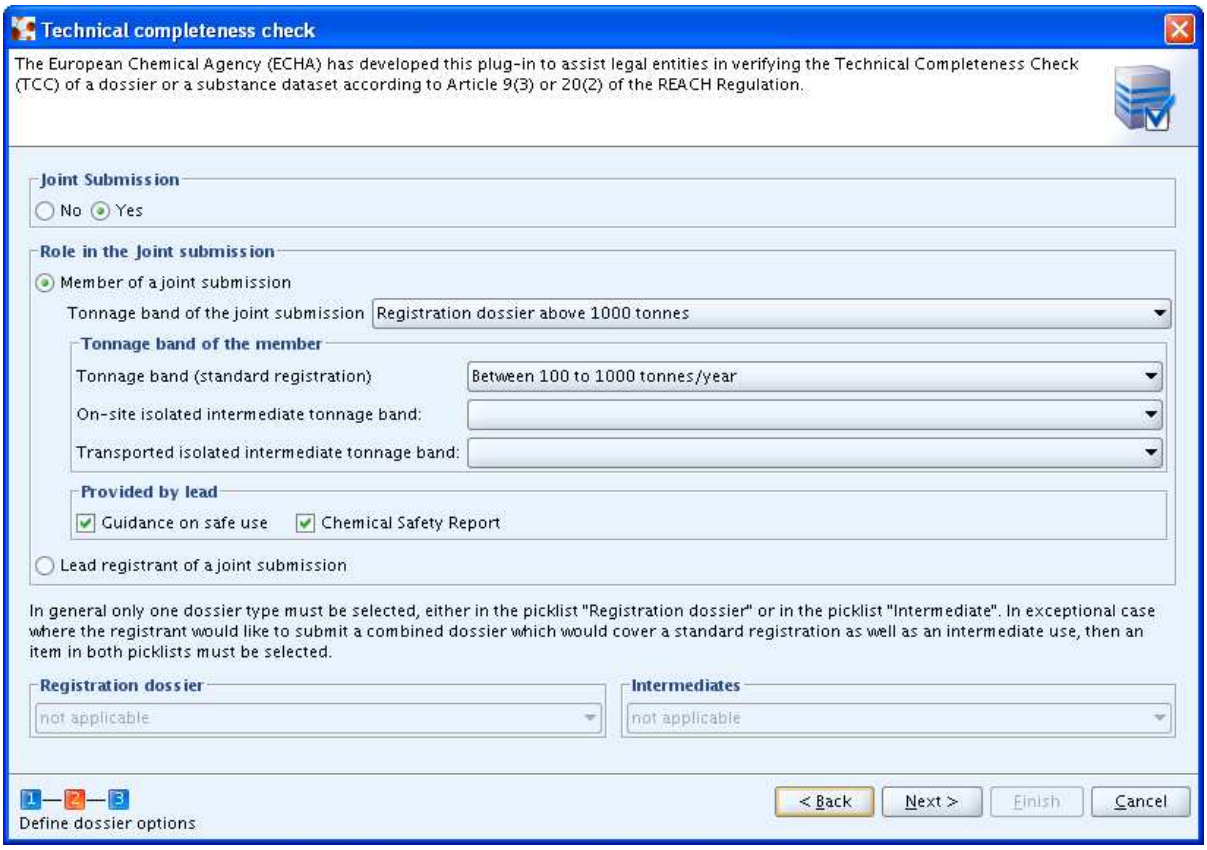

Technical completeness check
The European Chemical Agency (ECHA) has developed this plug-in to assist legal entities in verifying the Technical Completeness Check (TCC) of a dossier or a substance dataset according to Article 9(3) or 20(2) of the REACH Regulation.
Joint Submission
No
Yes
Role in the Joint submission
Member of a joint submission
Tonnage band of the joint submission
Registration dossier above 1000 tonnes
Tonnage band of the member
Tonnage band (standard registration)
Between 100 to 1000 tonnes/year
On-site isolated intermediate tonnage band:
Transported isolated intermediate tonnage band:
Provided by lead
Guidance on safe use
Chemical Safety Report
Lead registrant of a joint submission
In general only one dossier type must be selected, either in the picklist "Registration dossier" or in the picklist "Intermediate". In exceptional case where the registrant would like to submit a combined dossier which would cover a standard registration as well as an intermediate use, then an item in both picklists must be selected.
Registration dossier
not applicable
Intermediates
not applicable
1—2—3
Define dossier options
< Back
Next >
Finish
Cancel

Figure 11: Selection of tonnage band for a joint submission member registration

⚠ **Note:** IUCLID 5.4 offers the possibility to claim confidential the information contained in the Safety Data Sheet (SDS), such as the registration number, the legal entity, and the outcome of the PBT assessment. These confidentiality claims will be charged and invoiced for all substances that require a SDS. As before, a business rule will check that all chargeable claims are supported by a justification. To determine whether the substance being registered requires a SDS or not, for joint submission member registrations that lack information on classification and/or PBT assessment, some input by the user may be needed. This information is indicated with the radio buttons that appear under the new heading 'Is a safety data sheet required for this substance?' in Step 2 of the TCC wizard (Figure 12).

The input is only asked when the substance dataset or dossier contains confidentiality claims on the safety data sheet information and the member dossier does not contain enough information to determine whether a SDS is required for the substance to be registered.

More information on the dissemination and confidentiality claims of SDS information can be found in the FAQ document "Questions and answers on dissemination and confidentiality claims of Safety Data Sheet information in IUCLID 5.4" available at: http://echa.europa.eu/support/faqs

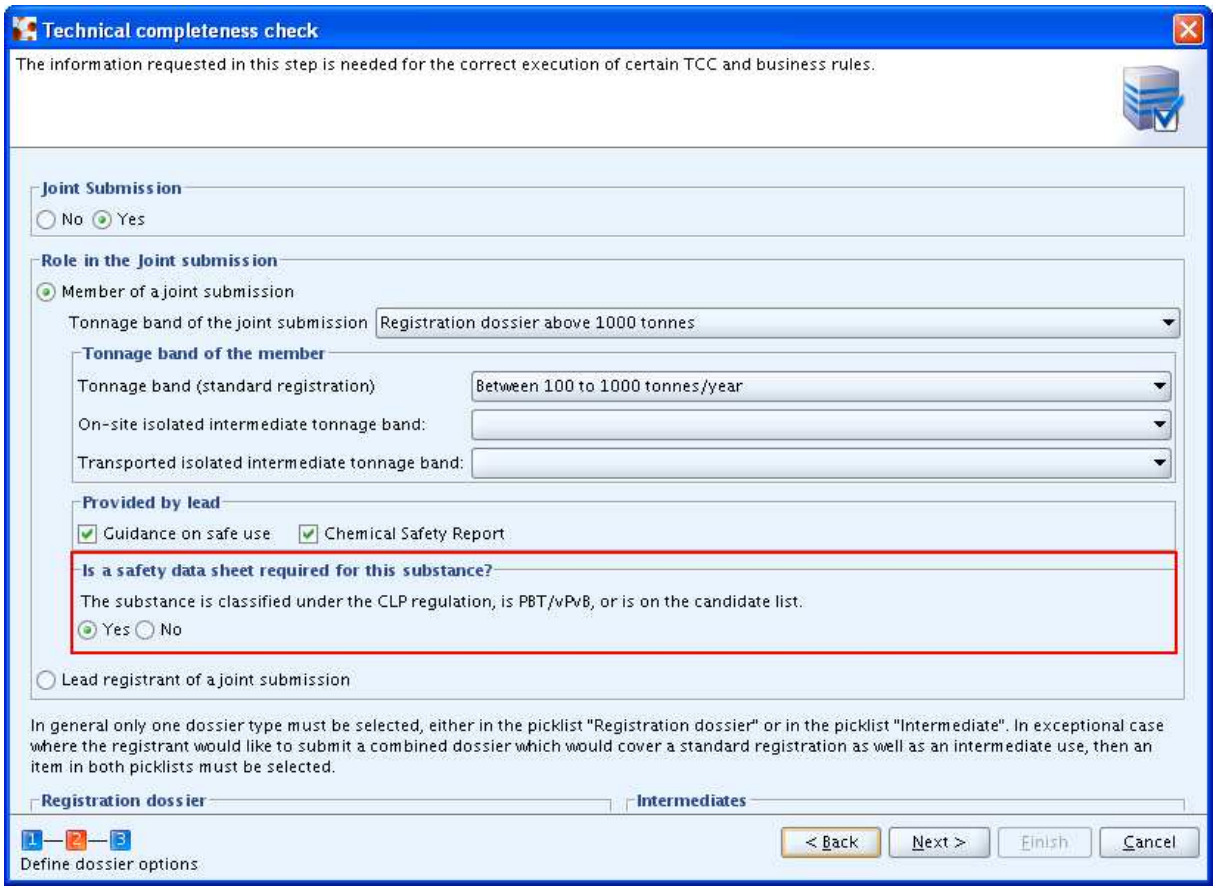

Technical completeness check
The information requested in this step is needed for the correct execution of certain TCC and business rules.
Joint Submission
No
Yes
Role in the Joint submission
Member of a joint submission
Tonnage band of the joint submission
Registration dossier above 1000 tonnes
Tonnage band of the member
Tonnage band (standard registration)
Between 100 to 1000 tonnes/year
On-site isolated intermediate tonnage band:
Transported isolated intermediate tonnage band:
Provided by lead
Guidance on safe use
Chemical Safety Report
Is a safety data sheet required for this substance?
The substance is classified under the CLP regulation, is PBT/vPvB, or is on the candidate list.
Yes
No
Lead registrant of a joint submission
In general only one dossier type must be selected, either in the picklist "Registration dossier" or in the picklist "Intermediate". In exceptional case where the registrant would like to submit a combined dossier which would cover a standard registration as well as an intermediate use, then an item in both picklists must be selected.
Registration dossier
Intermediates
1—2—3
Define dossier options
< Back
Next >
Finish
Cancel

Figure 12: Indication of whether a safety data sheet is needed - joint submission member registration

After having completed Step 2 of the TCC wizard the 'Next' button becomes active. Clicking on the 'Next' button will run the TCC rules according to the selected parameters and display the results in Step 3.

4.3 STEP 3: Interpretation of the TCC results table

In step 3 of the TCC wizard, the outcome of the performed check is displayed (Figure 13). The different parts of the results display are further described in the following subsections. While the screenshots are focussed on a dossier type with technical completeness check, the interpretation of the results as described below is also valid for dossier types with only SID and/or BR check.

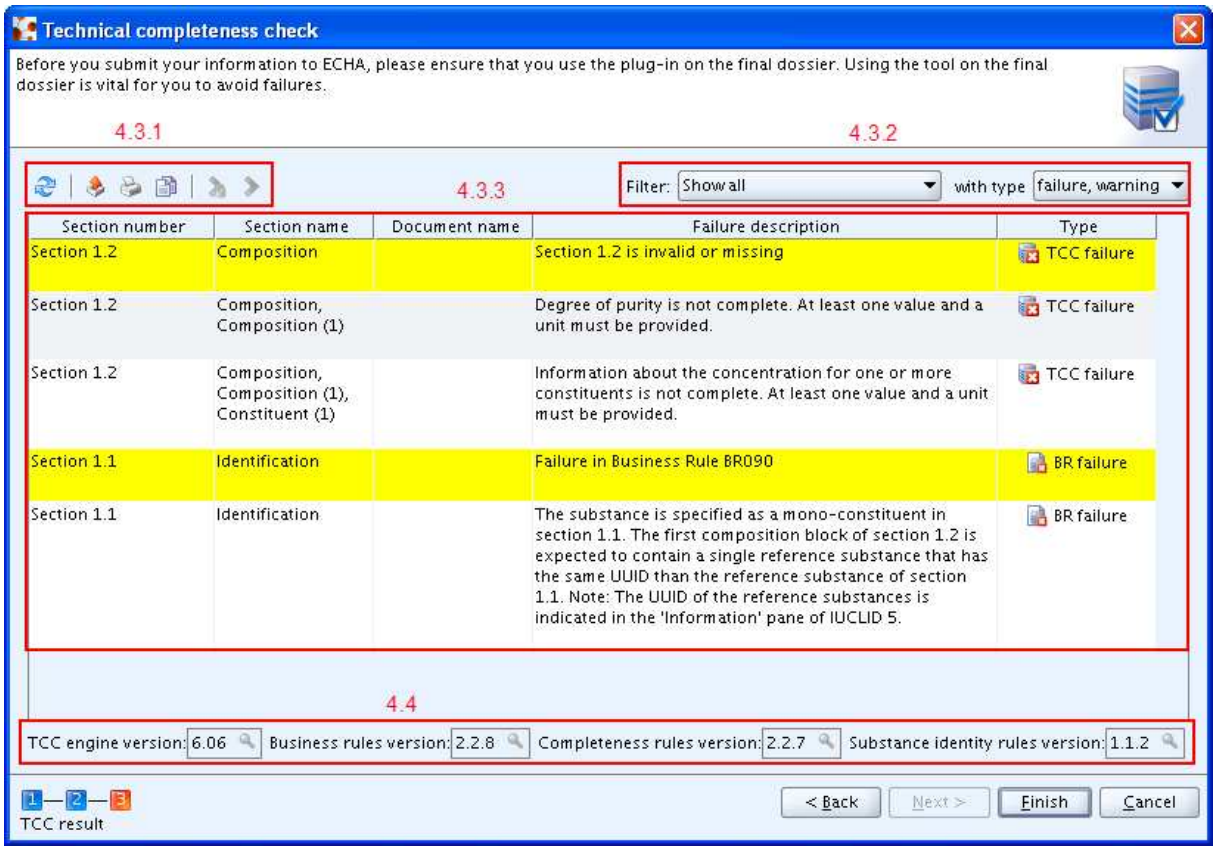

Technical completeness check
Before you submit your information to ECHA, please ensure that you use the plug-in on the final dossier. Using the tool on the final dossier is vital for you to avoid failures.
4.3.1
4.3.2
4.3.3
Filter: Show all
with type failure, warning
Section number
Section name
Document name
Failure description
Type
Section 1.2
Composition
Section 1.2 is invalid or missing
TCC failure
Section 1.2
Composition, Composition (1)
Degree of purity is not complete. At least one value and a unit must be provided.
TCC failure
Section 1.2
Composition, Composition (1), Constituent (1)
Information about the concentration for one or more constituents is not complete. At least one value and a unit must be provided.
TCC failure
Section 1.1
Identification
Failure in Business Rule BR090
BR failure
Section 1.1
Identification
The substance is specified as a mono-constituent in section 1.1. The first composition block of section 1.2 is expected to contain a single reference substance that has the same UUID than the reference substance of section 1.1. Note: The UUID of the reference substances is indicated in the 'Information' pane of IUCLID 5.
BR failure
4.4
TCC engine version: 6.06
Business rules version: 2.2.8
Completeness rules version: 2.2.7
Substance identity rules version: 1.1.2
1 2 3
TCC result
< Back
Next >
Finish
Cancel

Figure 13: TCC results display (the numbering corresponds with the following subsections)

4.3.1 TCC results toolbar

	Refresh the TCC result (only for substance datasets)
	Export the result list as xml. All the TCC results are exported in a XML file.
	Print the TCC result
	Copy the TCC results (could be pasted to Excel, Word…)
	Navigate to the document in the dossier If you select any row and press this button, it will open the dossier which was checked at the corresponding section.
	Navigate to the document in the substance dataset If you select any row and press this button, it will open the substance which was checked (or the one that was used to create your dossier) at the corresponding section. This option is not available if you were checking a dossier but the substance dataset that was used to generate that dossier is not in your IUCLID 5 database.

Tip: A double click on any row of the TCC results table has the same effect than clicking on the navigation buttons and . As a consequence a double click on a specific row will directly open the substance/dossier at the corresponding section.

4.3.2 Filtering the results table

Show all	All result items are displayed without filtering.
Only TCC rules	Only results with the level 'TCC failure' ( ) and 'TCC warning' ( ) are displayed in the results table.
Only Business rules	Only results with the level 'BR failure' ( ) and 'BR warning' ( ) are displayed in the results table.
Only Substance Identity rules	Only results with the level 'SID failure' ( ) and 'SID warning' ( ) are displayed in the results table.
failure, warning	Both failures and warnings are displayed in the results table.
failure	Only the failures are displayed in the results table, not the warnings.

When the TCC plug-in is run on a dossier or substance dataset, there are six types of messages that can be displayed, depending on the dossier template selected: Technical Completeness Check warnings and Technical Completeness Check failures; Business Rules warnings and Business Rules failures; Substance Identity Check warnings and Substance Identity Check failures. TCC messages appear only for registration and PPORD dossiers or substance datasets. SID messages appear only for inquiry dossiers or substance datasets. BR messages appear for all dossier types supported by the plug-in, as well as for substance datasets of the type registration, PPORD notification or inquiry.

TCC failures

TCC failure messages correspond to the Technical Completeness Check carried out at ECHA. If you submit your dossier without correcting the issues mentioned in the TCC failure messages, your dossier will fail the TCC in REACH-IT. These messages are flagged with the icon.

TCC warnings

A TCC warning is not an indication of that your dossier will fail the TCC, but it indicates that some information that should normally be in your registration dossier is lacking. Therefore, you are advised to correct the issue that raised the warning message, since it could have implications for the compliance of your dossier.

BR failures

A BR failure in the plug-in is associated with a BR step failure in REACH-IT. If you submit a dossier without correcting the issue mentioned in the message, your dossier will fail the business rules check during the submission process.

BR warnings

A BR warning does not directly translate into a BR step failure in REACH-IT, but it indicates that some information that should normally be in your dossier is missing. Therefore, you are advised to correct the issue that raised the warning message, since it could have implications for the compliance of your dossier.

SID failures

A SID failure informs you of substance identity deficiencies detected by the plug-in. You are therefore highly advised to correct any SID failure displayed.

SID warnings

A SID warning displays important recommendations on the substance identity information to be reported. You are highly recommended to address any SID warning which is relevant for the substance for which the substance dataset or dossier is prepared.

4.3.3 TCC results table

The rows highlighted in yellow in the TCC results table indicate the sections of the dossier/substance that gave rise to the failure/warning, or in the case of a BR/SID failure, the failing section and the number of the rule.

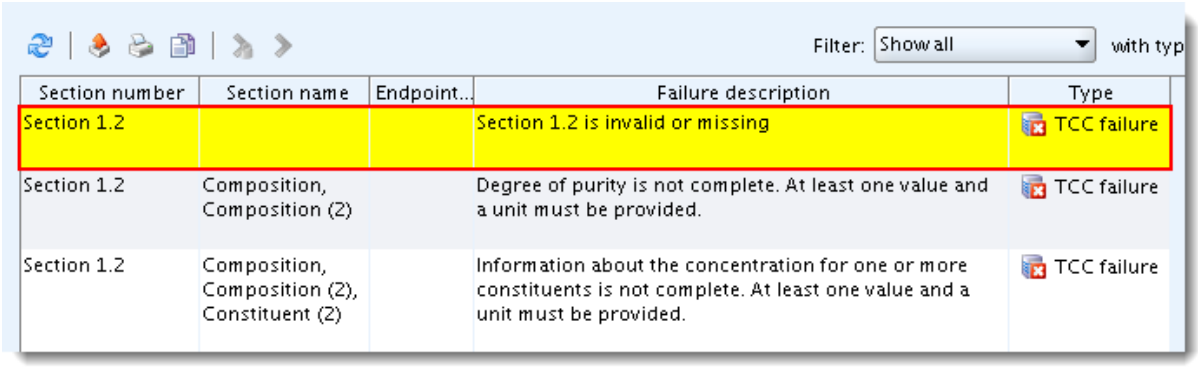

Filter: Show all
with typ
Section number
Section name
Endpoint...
Failure description
Type
Section 1.2
Section 1.2 is invalid or missing
TCC failure
Section 1.2
Composition, Composition (2)
Degree of purity is not complete. At least one value and a unit must be provided.
TCC failure
Section 1.2
Composition, Composition (2), Constituent (2)
Information about the concentration for one or more constituents is not complete. At least one value and a unit must be provided.
TCC failure

Figure 14: Yellow rows of the TCC results table

The rows in grey or white indicate the fields of the dossier/substance that need to be filled in to correct the failure/warning.

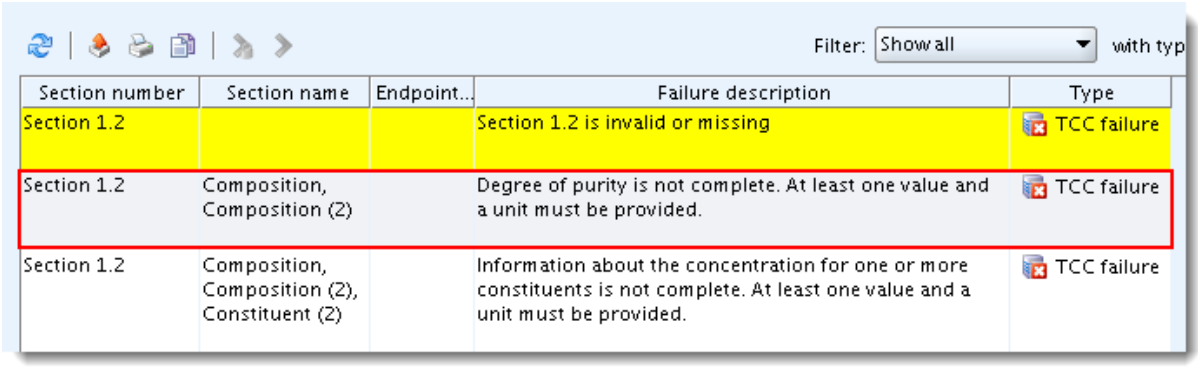

Filter: Show all
with typ
Section number
Section name
Endpoint...
Failure description
Type
Section 1.2
Section 1.2 is invalid or missing
TCC failure
Section 1.2
Composition, Composition (2)
Degree of purity is not complete. At least one value and a unit must be provided.
TCC failure
Section 1.2
Composition, Composition (2), Constituent (2)
Information about the concentration for one or more constituents is not complete. At least one value and a unit must be provided.
TCC failure

Figure 15: Grey/white rows of the TCC results table

A right mouse click on the results table opens the following menu:

Print table	The whole TCC result table will be printed.
Copy table	The whole TCC result table will be copied in the windows clipboard and can be pasted in Excel or Word, for instance.
Go to referenced document (dossier data)	This option will open the dossier that was checked with the plug-in.
Go to referenced document (raw data)	This option will open the substance dataset that was checked with the plug-in (if available in your IUCLID 5 database).

Tip: At step 3 of the TCC plug-in (results table), if you are running the TCC on a substance dataset, it is possible to interactively correct/modify the dataset while keeping the TCC results table open. After obtaining the TCC results table in step 3:

- Click on the toggle button to hide the TCC plug-in window, or move the plug-in window aside by dragging with the mouse

- Correct the indicated failure in the substance dataset

- Click on the save button in the IUCLID 5 toolbar

- Click on the toggle button to show the TCC plug-in window if you had hidden it

- Click on the refresh button of the TCC plug-in window to see if the failure description is still present.

Specific cases where failures indicated by the TCC plug-in may be disregarded:

There are cases where a TCC failure is listed in the TCC result table even if the dossier may be technically complete. These TCC failures do not mean that the dossier will necessarily fail the TCC but that a manual intervention will be needed from ECHA side in order to verify completeness. This is the case, for instance, with the following TCC failure:

- **Dossier header**: You are a member of a joint submission and your dossier contains an opt-out. If your tonnage band is higher than the tonnage band of the joint submission, ECHA will check that your additional information requirements have been fulfilled. If your tonnage band is not higher than the tonnage band of the joint submission then this message can be disregarded.

When no TCC/BR/SID failures are found in the dossier or the substance dataset, this is reported by the following TCC/BR/SID warning messages:

- **TCC:** Your dossier/substance dataset is considered as complete for the indicated tonnage band. However, please note that the completeness check performed by ECHA might include additional checks as for instance the relationship with other dossiers (e.g. lead versus member). These additional checks could potentially lead to different conclusions from those indicated by this tool. The use of the TCC tool is without prejudice to the obligation to submit a dossier that fulfils all relevant legal requirements.
- **BR:** No BR failures were detected by the plug-in. Please note that some of the business rules can only be checked at dossier level. Also note that due to technical reasons, the BR check performed by the plug-in does not cover all business rules checked at ECHA.
- **SID:** No substance identity failures were detected by the plug-in. Please note that this tool does not provide an assessment of the adequacy of the information reported. The use of this tool is without prejudice to the expert assessment carried out by ECHA to establish the adequacy of the information required under Annex VI p. 2 of the REACH Regulation.

Note: When updating a registration that was previously a notification under Directive 67/548/EEC for another reason than a tonnage band update, less information is required than for a standard dossier. The minimum information to be provided in this case is described in Annex 4 of Data Submission Manual 5 'How to complete a technical dossier for registrations and PPORD notifications'. The TCC plug-in does not offer the possibility to verify the completeness of only these reduced information requirements, but will check the full requirements for the selected tonnage band. As a consequence, the TCC plug-in can be used to check the completeness of these dossiers but only the TCC failures/warnings related to the information requirements indicated in Annex 4 of Data Submission Manual 5 could be a reason for considering the dossier as incomplete. The manual is available at http://echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/data-submission-industry-user-manuals.

Note: As stated in section 1, the check performed by the TCC plug-in does not cover all of the verifications carried out on a dossier submitted to ECHA. It is the responsibility of the submitter to ensure that the dossier fulfils the appropriate data requirements and to monitor the outcome of the submission process in REACH-IT.

4.4 TCC version information

When launching the TCC plug-in, in step 1 there is a plug-in version checker at the bottom of the plug-in window. The version checker verifies the version of the currently installed TCC plug-in and displays a warning message if a newer version is available on the IUCLID 5 website. To get the version checker working an internet access needs to be established. In case a proxy server is necessary for the internet access this can be defined by pressing the plug-in checker button:

Figure 16: Message for failed version check

Afterwards, a configuration popup window will appear where you will be able to define, if necessary, a proxy hostname and a port. The vendor URL is the URL from the IUCLID 5 website which is used for the online check. The definitions are stored for each user on the server. To reset the default value for the vendor URL just press 'Reset to default URL' below the vendor URL input field.

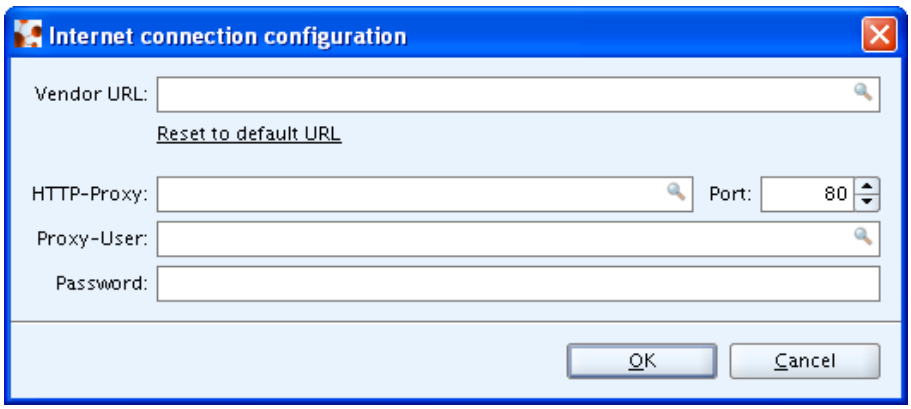


Figure 17: Internet connection configuration

If the plug-in is up to date the following status is displayed:

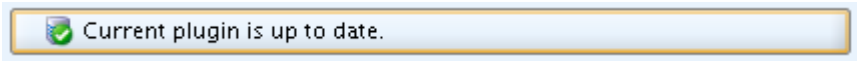


Figure 18: Message for plug-in up to date

If a newer TCC plug-in is available for update the following status is displayed:

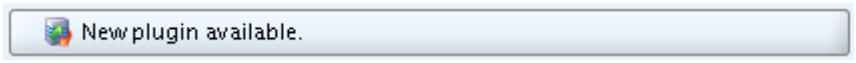


Figure 19: Message when new plug-in is available

In this latter case the new TCC plug-in should be downloaded from the IUCLID 5 website (the previous one needs to be removed and the new one installed).

In step 3 of the TCC plug-in wizard, below the TCC results table, the version information for the TCC engine, the Business rules, the Completeness check rules and the Substance identity rules are displayed. In order to verify that you are using the latest version of the TCC plug-in, you may compare these version numbers with the ones listed on the download page of the TCC plug-in on the IUCLID 5 homepage.

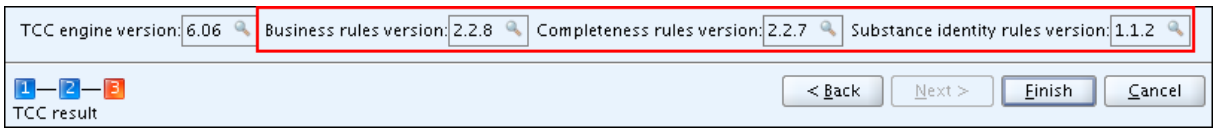


Figure 20: TCC version information

European Chemicals Agency

IUCLID 5 Support

Technical Completeness Check plug-in Manual
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http://iuclid.eu